

## Changing trends in informed consent

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**Abstract:** Consent is defined as the “voluntary agreement to or acquiescence in what another person proposes or desires”. In the context of medical practice it is now universally accepted that every human being of adult years and of sound mind has the right to determine what shall be done with his or her own body. Informed consent is now a central part of medical ethics and medical law. There has been a change in the public’s expectations of their role in medical decision making. The paternalistic approach by doctors is no longer acceptable. Today the patient has the right to receive and the doctor the obligation to give sufficient and appropriate information so that the patient can make an informed decision to accept or refuse a treatment option. This has led to higher standards of practice in the process of informed consent taking. Consent taking is both a legal and moral requirement. Failure to comply with standards of practice can result in criminal prosecution, civil litigation or disciplinary action by the relevant professional authority. Consent taking is a process and not merely a one-off affixation of the patient’s signature on a consent form. It involves a continuous discussion to reflect the evolving nature of treatment from before the treatment is given to the post-operative or discharge period. The regulatory authorities in many countries have established standards for consent taking which would include the capacity of the patient, the person who should seek consent, the information to be provided and the necessary documentation.

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### Introduction

Consent is defined as the voluntary agreement to or acquiescence in what another person proposes or desires and informed consent is where consent is given based on an adequate explanation of procedures and risks involved as well as anticipated outcomes. In Britain

the term “duty to warn” is also used. There has been a change in the practice of consent taking over the years. The changing trend has been shaped by public outrage resulting from research atrocities as well as decisions made by courts of law. The concept of informed consent is of relatively recent origin. It was not mentioned in the Hippocratic tradition.<sup>1</sup> Conversely the practice of doctors had for many centuries been based on benevolent deception and non-disclosure and the doctor-patient relationship was essentially paternalistic in which the doctor concealed important diagnostic and prognostic information from the patient.

### Research atrocities

During the Second World War, both the Germans and the Japanese committed research atrocities. Nazi doctors experimented on prisoners in concentration camps. Research undertaken included the deliberate infection of wounds to test newly developed antimicrobial agents, the shooting of prisoners for the study of gunshot injuries and the starvation of inmates to study the effects of malnutrition and dehydration.<sup>2</sup> The Japanese established Unit 731 in Ping Fan, Manchuria. This was a covert biological and chemical warfare research and development unit of the Imperial Japanese Army where lethal human experimentation were conducted during the Second Sino-Japanese War and World War II.<sup>3</sup>

Other unethical research projects included the Tuskegee Study in the United States where black subjects with syphilis were not treated in order to observe the natural history of the disease. This research project began in 1932 and continued until 1972, long after effective cures has been established for the treatment of syphilis.<sup>4</sup> Another instance of unethical research was the Willowbrook Study where retarded children in a home in New York were deliberately infected with Hepatitis A virus between 1956 – 1970 in an effort to develop a vaccine. Although the parents of the children consented to the study, the consent was obtained under duress as consent to participate was made a condition for admission to the home.<sup>5</sup>

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## Research Codes of Ethics

As a result of the wartime research atrocities the Nuremberg Code of ethical behaviour was established in 1947.<sup>6</sup> The first requirement under this code is that the voluntary consent of the human subject is absolutely essential. In 1964 the World Medical Association developed the Declaration of Helsinki which aimed to address deficiencies in the Nuremberg Code.<sup>7</sup> The Declaration of Helsinki has since been revised six times; most recently in 2008.

## Landmark court cases

The decisions of the court in cases of medical litigation have also helped to shape the practice of informed consent. Several cases in the United States, the United Kingdom, Australia and Malaysia are described below.<sup>8,9,10</sup>

### *The Schloendorff Case (1914)*

A surgeon removed a fibroid from the patient, Mrs Schloendorff, without her consent during an examination under anaesthesia. Mrs Schloendorff sued and the court found in her favour. This case is important because this was the first time, a court had established a patient's right to give voluntary consent to any medical procedure. The judge in this case ruled that, "Every human being of adult years and sound mind has the right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable for damages...."

### *The Salgo Case (1957)*

Mr Salgo suffered paralysis following an aortogram. Although he consented to the procedure he claimed he was not informed of this possible complication. In this case, the court was of the opinion that "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment." This case is considered landmark as it established the basis of informed consent.

### *The Canterbury Case (1972)*

Mr Canterbury suffered paralysis after back surgery. He sued the surgeon for not informing him of all potential risks of the operation even though he (Mr Canterbury) did not ask. The court ruled that "It is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie". The doctor is obliged to discuss all material risks with the patient. The court defined risk as material "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to (it)". This decision sets the standard or level of disclosure and advocated the use of the "reasonable person standard".

### *The Bolam Case (1957)*

Mr Bolam was a patient at the Friern Hospital (a psychiatric facility) in London. He was given electroconvulsive therapy without muscle relaxants or being strapped. As a result he suffered from fractures. He sued the hospital for negligence but lost as the practice was consistent with medical opinion at that time. The court ruled that "a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art..." This decision is considered landmark as it sets the standard in negligence cases as that which is accepted by the profession.

### *The Sidaway Case (1985)*

The patient suffered paralysis after spinal cord decompression. The patient claimed negligence as she had not been informed of the risk of this outcome. The House of Lords rejected the appellants claim by a majority of 4 -1, as a respectable body of medical opinion agreed that it was not necessary to warn a patient of every risk. In other words the House of Lords ruled that the Bolam test applied even to the question of consent. Lord Scarman, the dissenting judge took a different view that in determining whether a doctor had given sufficient advice, professional practice should not

be determinative and the standard should be based on whether a reasonably prudent patient if told of the risk would attach significance to it.

#### *The Bolitho Case (1997)*

Patrick Bolitho, a 2-year old child who was admitted to St Bartholomew's Hospital in London for croup suffered extensive brain damage following respiratory failure. The parents sued for negligence on the grounds that early intubation may have prevented the event. At the trial medical experts gave conflicting opinions. The House of Lords held that there would have to be a logical basis for the opinion not to intubate. This would involve a weighing of risks against benefit in order to achieve a defensible conclusion. In other words, the body of medical opinion relied upon by the doctor had to have a "logical basis".

#### *The Whitaker Case (1993)*

Maree Whitaker has been almost blind in her (R) eye for 40 years. An ophthalmologist she consulted offered to operate on the eye to improve both vision and appearance. After the operation she suffered sympathetic ophthalmia in her (L) eye (a risk of 1 in 14000). She became blind in both eyes as the (R) eye vision had not improved. She sued the surgeon and the Australian High Court found in her favour. The six High Court judges ruled that "a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient if warned of the risk, would be likely to attach significance to it." The court had therefore rejected the Bolam test in the matter of informed consent and had used the "*particular patient*" standard.

#### *The Foo Fio Na case (2006)*

In this Malaysian case, the patient suffered dislocation of the cervical vertebrae following a car accident. An operation to reduce the dislocation and stabilise the

vertebrae resulted in paralysis. The patient maintained that had she been warned of the risks involved she would not have readily agreed to undergo the operation. The court found in her favour and was of the opinion that the Whitaker test would be a more appropriate and a viable test than the Bolam test. This is a very important decision for the practice of medicine in Malaysia as the standard to be applied would be the "particular patient" standard rather than the opinion of the profession.

#### **Informed Consent Today**

Informed consent is now central to good medical practice. It is both a legal and moral requirement and forms an important aspect of the doctor-patient relationship. Failure to obtain consent can have dire consequences. It may result in criminal prosecution for battery which is the harmful or offensive touching of another person. It may also be viewed as medical negligence resulting in litigation. It is also considered a breach of ethical behavior and the practitioner may be summoned by the professional regulatory authority for infamous conduct in a professional respect or gross professional misconduct. Failure to disclose in order to prevent the patient from worrying is not a defensible reason. In Malaysia guidelines on consent have been developed by the Malaysia Medical Council and formally adopted in January 2013. This is available on the Internet.<sup>11</sup>

There are several key elements in informed consent. Disclosure must be adequate and the patient must be informed of all material risks. The adequacy of disclosure in Malaysia is judged by the "particular patient" standard. The more frequent the risk, the greater the obligation to discuss it. However even uncommon risks of great potential seriousness should be disclosed. Apart from risks the doctor is also obliged to discuss other relevant issues with the patient including diagnosis and prognosis, uncertainties, treatment options, benefits, risk of non-treatment, patient's right to refuse and seek a second opinion, payments, experience of the doctor, and any conflicts of interest.

The understanding by the patient is another important element in the process of obtaining informed consent. Physicians have a duty to take reasonable steps to ensure the patient understands the information, particularly where there may be language difficulties or emotional issues involved. When interpreters are used, the physician has an obligation to ensure that the interpreter has conveyed the information to the patient accurately. Printed material may be used to supplement but not supplant the explanation given by the doctor. The patient must be given sufficient time to digest the information given.

All patients who give informed consent must be competent to make the decision. Competence is defined as the capacity of the patient to give consent. In many jurisdictions capacity is based on the legal age of majority which is 18 years in Malaysia. In some jurisdictions the maturity of the person has replaced chronological age. In Canada a minor may give consent if his physical, mental and emotional development allows for a full appreciation of the nature and consequences of the proposed treatment as well as the refusal of such treatments.<sup>12</sup> Patients must also have the mental capacity to give consent. Often the mental capacity is regulated by legislation and in Malaysia the relevant act would be the Mental Health Act 2001. However psychiatric illnesses do not automatically preclude a person from giving consent. A mental capacity assessment may be necessary to establish capacity in some cases. In cases where the patient is deemed to lack competence a substitute decision maker (usually a person with “parental responsibility”) may give the consent. In all cases the doctor must always act in the best interest of the patient. Where there are doubts, doctors should consult their peers and if necessary seek legal advice.

Another key element is the autonomy of the patient in that the patient’s agreement must be entirely voluntary. It must be made clear to the patient that he has the right to refuse treatment but the consequences of non-treatment have to be clearly explained to him.

### **Types of consent**

Implied consent is where consent is implied either by the words or the behaviour of the patient or by the circumstances under which treatment is given. The extent to which consent was implied may later become a matter of disagreement; “implied consent” per se is merely an impression and would not protect the doctor in the event of any litigation. Acquiescence is not necessarily consent.

Expressed consent may be oral or written. Oral consent may also be a cause for possible subsequent disagreement. A written consent is taken for procedures with significant risks of adverse events. A consent form is used but it should be remembered that the form is merely evidence of the process but not the process itself. The consent form is of little value if the process is inadequate or flawed. When informed consent is called into question, a doctor’s notes in the case records will be of greater value for defence purposes in court than the consent form.

### **Person obtaining consent**

The person who should obtain consent is normally the doctor providing the treatment. In some instances the doctor recommending the treatment may be the person who obtains the consent. In practice the task of obtaining consent may be delegated to a junior doctor or a nurse. If this is the case it is absolutely essential that the delegated person should have suitable training and qualifications to have sufficient knowledge of the procedure and risks involved and be able to address all of the patient’s questions and concern.

### **Exceptions to informed consent**

There are some instances where informed consent may not be possible. These instances often relate to medical emergencies and public health emergencies. In Malaysia the Infectious Diseases Act 1988 allows for an authorized officer to direct any person in an infected

area to treatment, immunisation, isolation, observation and surveillance.

## Conclusion

There has been a changing trend in the practice of informed consent. Patient autonomy is now considered paramount. The approach today is less paternalistic and more patient-centred. Informed consent is a process and there is a need to ensure adequacy of disclosure especially about all material risks of the procedures to be performed. Failure to obtain informed consent is a serious omission and can lead to criminal prosecution, medical negligence and action by the Medical Council for gross professional misconduct.

## REFERENCES

1. Miles SH. Hippocrates and Informed Consent. *Lancet* 2009; 374: 1322-3.
2. Pence GE. *Medical Ethics: Accounts of cases that shaped and defined medical ethics*. Boston: McGraw Hill, 2008.
3. Gold H. *Unit 731: Testimony*. Boston: Tuttle Publishing, 2004.
4. Holmes-Farley SR, Grodin MA. Socially responsible research. *American J Law Med* 1998; 24: 153-62.
5. Ingelfinger FJ. Ethics of experiments in children. *New Engl J Med* 1973; 288: 791-2.
6. Shuster E. Fifty years later: the significance of the Nuremberg Code. *New Engl J Med* 1997; 337: 1436-40.
7. World Medical Association. Declaration of Helsinki. Available at: <http://www.wma.net/en/20activities/10ethics/10helsinki/>. Accessed on 30 May 2013.
8. Osman H. History and development of the doctrine of informed consent. *Internat Electronic J Hlth Educ* 2001; 4: 41-7.
9. Chao HT. 5<sup>th</sup> Chao Tze Cheng Memorial Lecture. Recent developments in formed consent. *Ann Acad Med* 2012; 41: 540-8.
10. Paola FA, Walker R, Nixon LL. *Medical Ethics and Humanities*. Sudbury : Jones and Bartlett, 2010.
11. Malaysia Medical Council. Consent for treatment of patients by registered medical practitioners. Available at: <http://mmc.gov.my/v1/docs/Consent%20Guidelines%2015012013.pdf>. Accessed on 30 May 2013.
12. Evans KG, Henderson GL. *Consent a guide for Canadian physicians*. 4<sup>th</sup> Edition. Ottawa: Canadian Medical Protective Association. 2006.